K090415
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Eminent Spine Fang Plate System

Premarket Notification

JUN - 1 2009

SUBMITTED BY	Eminent Spine 16001 Ronald Reagan Blvd Leander, TX 78641	
ESTABLISHMENT REGISTRATION NUMBER	Pending	
OWNER/OPERATOR NUMBER	10028153	
CONTACT PERSON	**Primary** Dave Freehill President/Co-Founder Phone: 512-259-9002 Fax: 512-259-9515	**Alternate** Steve Courtney, M.D. President/Co-Founder Phone: 214-415-5243 Fax: 972-250-5651
SUBMISSION PREPARED BY	Lisa Peterson QA Consulting, Inc. Phone: 512-507-0746	
DATE PREPARED	February 13, 2009	
CLASSIFICATION NAME	KWQ 888.3060- Spinal Intervertebral Body Fixation Orthosis	
COMMON NAME	Buttress Plate	
PROPRIETARY NAME	Eminent Spine Fang Plate System	
PREDICATE DEVICE(S)	MacroPore OS Spinal System (K010911)	

SUBSTANTIAL EQUIVALENCE

The Eminent Spine Fang Plate System was determined to be substantially equivalent to the MacroPore OS Spinal System (K010911).

DEVICE DESCRIPTION

The Eminent Spine Fang Plate System consists of a plate and screw. The plate, which is available in two sizes (24mm and 27mm), is designed with an 8° bend to conform to the anatomy of the anterior spine to prevent migration or expulsion of allograft or autograft in the thoracolumbar to S1 spinal region. Additionally, the plate features two "fangs" that prevent rotation, and a screw slot for final fixation. The 5.5mm screws are available in 20mm and 25mm lengths.

INDICATIONS:

The Eminent Spine Fang Plate System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures of the thoracolumbar to S1 spinal region as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

MECHANICAL TEST DATA

Mechanical test results demonstrate that the Eminent Spine Fang Plate System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eminent Spine
% Mr. Dave Freehill
President/Co-Founder
16001 Ronald Reagan Boulevard
Leander, Texas 78641

JUN - 1 2009

Re: K090415
Trade/Device Name: Eminent Spine Fang Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: May 13, 2009
Received: May 14, 2009

Dear Mr. Freehill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K090415

Device Name: **Eminent Spine Fang Plate System**

Indications for Use:

The Eminent Spine Fang Plate System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures of the thoracolumbar to S1 spinal region as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090415